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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Oleg Ilich Epshtein
Title of Invention : A Medicinal agent and method for curing
erectile dysfunction
Date Filed : January 22, 2005
Serial No. : 10/522,650
Examiner : Ouspenskii, I.
Art Unit : 1644
Confirmation No. : 7546

DECLARATION UNDER 37 CFR 1.132

I, O. I. Epshtein, Dr. Sc, do hereby declare as follows:

1. My name is Dr. Oleg I. Epstein. I am a widely recognized scientist in the fields of immunology and homeopathy. I authored over 100 articles in the peer-reviewed journals.

2. The company I lead, Materia Medica Holdings, successfully sells the product covered by the above-identified application 10/522,650. I am the inventor of the '650 application.

3. I reviewed all references cited by the Examiner in the final Office Action mailed on February 18, 2009, namely, *Salerno, Davenas et al.*, and *Feldman et al.* I am familiar with the *Epshtein et al.* article cited by the Examiner.

4. It is my understanding that the Examiner argued that one skilled in the art would have a reason to use the antibodies to NO synthase of *Salerno* in the manner disclosed in *Epshtein et al* and/or *Davenas et al.*, based on the motivation of *Feldman, et al.* and have reasonable expectation of success that homeopathic dilution of antibodies to NO synthase will work for treatment of erectile dysfunction based on the information in the cited references.

5. It is my opinion that one skilled in the art would not expect the homeopathic technology to be applied to antibodies of *Salerno* and then achieve any

reasonable treatment objectives. Quite simply, it is my opinion, as one well skilled in the art, that the information available in the art at the time the '650 application was filed was not sufficient to create an expectation of success in any reasonable field of treatment based on disclosures of *Salerno*, *Davenas et al.*, *Feldman et al.* and *Epshtein et al.*

All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of any patent application issuing thereon.

Dated: August 13, 2008

Dr. Oleg I. Epstein